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Good morning. My name is Denise Keane and I am the General Counsel for Philip Morris U.S.A. Today I'd like to touch very briefly on some of the higher-profile regulatory and litigation issues facing our company.

I'd like to begin by giving you a brief look at the current regulatory environment, focusing on the FDA, but also with a couple of side trips over to EPA and OSHA. I'll then move on to current smoking and health litigation and the implications we see for PM USA.

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The federal Food and Drug Administration -- FDA -- is given the responsibility by an act of Congress for regulating foods, drugs, medical devices and cosmetics.

Cigarettes have always been viewed by the FDA basically as "none of the above." In fact, in the past when activist groups have attempted to force the FDA to regulate cigarettes as drugs, the FDA has denied or ignored their petitions, and FDA has successfully defended its position in court.

There have been 20 attempts in Congress to give FDA regulatory authority over tobacco, and not one of those proposals has passed.

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Enter FDA Commissioner David Kessler, who was obviously not satisfied with that regulatory scheme and who wants to extend FDA's regulatory power and domain to include tobacco.

In March, 1994, Commissioner Kessler announced that if cigarette companies were shown to control nicotine levels in order that cigarettes provide levels of nicotine that are "addictive," then FDA could regulate cigarettes as a drug under the current Food, Drug and Cosmetic Act.

On July 12 of this year, the FDA announced that it had decided to declare nicotine a "drug" and cigarettes "drug delivery devices," thereby subjecting cigarettes to FDA regulation.

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This decision was not the result of independent evidence, but based on FDA's own analysis and agenda.

In August, Commissioner Kessler took his case for FDA regulation of tobacco to President Clinton, this time adding the argument that such regulation was needed to curb smoking by minors.

Kessler -- who is very adept at public relations -- chose to call such smoking a "pediatric disease."

On August 10, President Clinton announced his agreement with FDA that tobacco products are devices subject to FDA regulation.

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~~The President permitted~~ FDA ~~to~~ submit a proposed rule that would severely restrict the ability of tobacco manufacturers to market, promote and advertise their products.

The proposed rule was published in the Federal Register on August 11th, with a 90-day public comment period to follow. After reviewing the public comments, FDA will seek to publish a final, enforceable rule.

President Clinton has said that the FDA's actions are aimed only at stopping minors from using tobacco products, but the specific regulations in the FDA proposal cast a much wider net.

The proposed rule would, among other things:

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- Prohibit all ads that appear in stores and other points of sale, and all direct mail ads to the home, except ads that are in a no-graphics, black-and-white-print only, format.

- Prohibit all self-service displays, all coupons sent through the mail, and all vending machines.

- Prohibit the sale or give-away of non-tobacco merchandise carrying a tobacco product brand name or other tobacco product identification, thereby eliminating such programs as Marlboro Adventure Team and Marlboro Country Store.

- Prohibit brand sponsorship of events, thereby eliminating such events as Marlboro Indy Car racing, Virginia Slims tennis.

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• Ban all outdoor advertising within 1,000 feet of schools and playgrounds.

• Ban all other outdoor advertising altogether, including ads on transportation and at sports facilities, unless the ads are in a no-graphics, black-and-white-print only, format.

• In addition, this restricted or so-called "tombstone" advertising format would also be required of any advertisement put in publications where 15 percent or more of the readership is under the age of 18.

• All cigarette advertising will have to carry not only the standard Surgeon General's warnings, but also a warning that states the product is a "nicotine delivery device" and perhaps another statement saying that "about one of three children who begin smoking will die from their smoking."

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• Require the tobacco industry -- and if you sell cigarettes one assumes you are counted as a member of that industry -- to pay $150 million per year to fund FDA approved ads urging minors not to smoke.

• But the FDA rules are not all bans, prohibitions and restrictions. There is permission granted too. States and localities are permitted to pass more restrictive laws beyond the requirements set up by FDA.

• Finally, if within seven years youth smoking has not fallen by 50 percent or more, FDA can take additional measures against the marketing, sale and promotion of tobacco products.

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If the FDA proposals were to take effect as they are presently constituted, the retail industry could well experience a drop in income of millions of dollars.

It could also experience a concomitant loss of thousands jobs, as convenience stores adjust to their loss of income by reducing their workforce.

The Tobacco Institute is commissioning a study to determine the exact economic impact that would occur if the FDA rules were to become operational. Once that study is complete, we will make sure that you receive the results.

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Moreover, if the rules were to take effect, you could also expect an in-store environment that is completely vulnerable to further FDA regulation of products as "drugs," beginning with beer.

Immediately after the FDA's proposed regulation was published in the Federal Register, Philip Morris and other members of the tobacco industry filed a lawsuit in North Carolina federal district court, charging that the FDA does not have the legal authority to regulate tobacco products.

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Steve Parrish, Philip Morris Companies Inc. Senior Vice President, Corporate Affairs, said at a press conference held after the suit was filed, that the lawsuit was, quote, "not about youth smoking. This lawsuit is about whether, in defiance of 80 years of clear precedent, David Kessler and the FDA can regulate cigarettes."

Steve went on to say, quote, "David Kessler's action can only be described as a Trojan Horse, set forward under the guise of preventing youth smoking. Make no mistake; the real agenda here is prohibition."

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While our law suit challenges the FDA's authority to regulate, another lawsuit filed on the same day by a coalition of groups from the advertising industry focuses on the violation of the First Amendment right to freedom of speech that is inherent in the FDA regulation.

John Fithian, counsel to the coalition, said, "regardless of how one feels about tobacco, such blatant disregard for our Constitution by the federal government is alarming."

These suits are in the preliminary stages, and we will keep you informed of any developments that occur in them.

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Before leaving the subject of FDA regulation, and FDA and presidential concern about youth smoking, I'd like to stress that Philip Morris U.S.A. has been actively engaged for decades in programs, policies and codes to prevent minors from smoking.

A little later, Ellen Merlo, Senior Vice President, Corporate Affairs, Philip Morris U.S.A., will discuss our most recent and most comprehensive initiative to have a major impact on preventing youth access to our products.

Ellen will also answer the "what can we do to help" kinds of questions that arise out of discussions of FDA regulation. In fact, if I know Ellen, she won't even wait for the questions, but will have strongly in mind what you can do to help and will share that information with you.

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Now let me turn to a suit we filed against the EPA in 1993, and that is still in progress. An interesting bridge between the FDA and the EPA suit is the fact that the same judge -- William Osteen, U.S. District Court, Middle District, North Carolina -- is handling both cases.

As you may recall, in January, 1993, the EPA issued a risk assessment classifying environmental tobacco smoke as a "Group A" or "known human" carcinogen.

Despite the fact that the EPA risk assessment has been subject to growing criticism, legislators and regulators continue to rely on the assessment as scientific justification for severely restricting or banning smoking in public places and the workplace.

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In June, 1993, we filed a lawsuit against EPA, in which we are challenging the scientific basis of EPA's risk assessment on environmental tobacco smoke. The case has been moving rather slowly, however, and no date has been set for trial. We feel good about this lawsuit and look forward to a trial on the merits.

Our view of the most likely outcome of the EPA issue is that the legitimate questions that we and others have raised should reduce the agency's credibility and its clout.

If we win our law suit, it will open up the potential to limit a wide range of threatened legislation and regulation that would unreasonably restrict smoking.

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Now let me touch on the federal Occupational Safety and Health Administration's attempt to create a new rule that would severely regulate smoking in the workplace.

The rule OSHA proposes is extremely harsh. The cost and space required to meet its standards would be prohibitive to most small businesses, so the proposed regulations would be, in effect, a de facto nationwide workplace smoking ban.

OSHA held public hearings on the proposed regulation from September 20, 1994 through March 13, 1995. The most likely outcome of the OSHA proposal is that, some time after the November 1995 deadline for additional public submissions on the rule, the agency will publish a revised rule.

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That revised rule could be subject to a second round of public comments and, possibly, public hearings. A final or revised rule is not likely until sometime in 1996.

We hope that the Agency, in the face of unprecedented public response to the proposed regulation, will eventually put forward a revised proposal that is less onerous.

Before leaving the topic of OSHA, let me take a moment to strongly applaud the efforts many of you in the c-store industry made in submitting public comments to OSHA regarding the negative impact of the proposed regulation on your businesses.

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OSHA received approximately 105,000 separate comments: each correctly addressed and submitted, as required, in quadruplicate.

Prior to this, the most public comments OSHA had ever received on any regulation it had ever proposed was about 4,000.

By a margin of 50 to 1, the public comments strongly opposed the workplace smoking ban OSHA wanted to put into effect.

Through that public outpouring, and the testimony before the OSHA hearings, some very important people now know that the OSHA proposal is unworkable.

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Those people include the director of OSHA, his boss the Secretary of Labor, his boss the President of the United States of America, and his boss the American People and the U.S. Congress.

And they also know, without a shred of doubt, that there are effective, fair, workable alternatives which involve choice and accommodation by employers and workers alike.

The last topic I will address today is the status of smoking and health litigation in the U.S. I will focus on the class action and Medicaid reimbursement lawsuits that were filed last year.

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A class action is a procedural device whereby one or more members of a group may sue as representative parties on behalf of all the members of the group. Class actions are intended to resolve -- in a single case -- disputes involving common questions and multiple parties.

Plaintiffs' lawyers see a number of advantages in bringing cases as class actions, including huge fees, work limited to one case rather than multiple cases, and financial stakes that can become so high for the defendants the plaintiffs are suing, that settlement possibilities and values are enhanced significantly for plaintiffs.

Indeed, very few product liability class actions have ever gone to trial for that very reason.

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The *Castano* case, in New Orleans, is probably the most famous of the current class-action tobacco cases. More than fifty law firms joined together to bring the suit.

In *Castano*, the theory of the plaintiffs case is that cigarette companies have "addicted" smokers and the ~~six~~ three named plaintiffs want to sue on behalf of everyone who is (or was) "dependent" on nicotine, whether living or dead.

The class definition is as broad as it seems. In the view of plaintiffs' counsel, every smoker and former smoker in the country may be a member of the class -- creating a class that could perhaps include upwards of 90 million people or more.

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Picking up on allegations that Dr. Kessler made, the plaintiffs claim that the tobacco companies have "controlled and manipulated the amount of nicotine in their cigarettes for the purpose and with the intent of creating and sustaining addictions to those products."

As a result of this conduct, the plaintiffs allege that they have become addicted to nicotine. They seek billions of dollars in damages.

We are optimistic about the outcome in *Castano* for the simple reason that we don't believe the plaintiffs can legally justify a class action.

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Although the judge in this case conditionally certified, in part, the *Castano* class, he made it clear that no damages could be awarded to a single plaintiff without an individual trial on the crucial issues of injury, causation, and reliance.

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We have appealed the partial certification ruling. ~~Our brief for that appeal is scheduled to be filed October 17.~~ In the larger legal picture, even if our appeal is denied, we would be able to use our affirmative defenses in every such trial. These are the very issues that have proven so successful over the years.

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At the same time that the class was certified, a stay of discovery was put into effect, but now that stay has been lifted, permitting very limited discovery.

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+ the Castano Action

Plaintiff lawyers have delivered subpoenas for documents to executives at ABC, to stock analysts, even to the lawyer who defended ABC in our libel suit against the network. Those subpoenas are being held in abeyance until protective orders requested by both RJR and Philip Morris are ruled upon.

I mentioned that in *Castano,* plaintiff lawyers are trying to make the case that tobacco companies manipulate the amount of nicotine in their cigarettes in order to addict smokers.

ABC tried to create controversy by foisting this same false notion upon the public in the network's "Day One" TV news magazine show.

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We sued ABC for libel, ~~and forced them to~~ admit their ~~premise~~ was without fact and ~~to~~ apologize several times to mass media audiences.

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PM Chairman Geoff Bible, summarizing the strength PM was operating from in that suit, said of ABC, "They lied, they know they lied, and we can prove it."

All of which is to say that the case the *Castano* Consortium of lawyers is trying to make is on very shaky ground, as ABC can attest.

A second class action, *Engle*, was filed in Miami. The *Engle* class is defined as:

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all United States citizens and residents and their survivors, who have suffered, presently suffer, or who have died from diseases caused by their addiction to cigarettes that contain nicotine.

Note that the *Engle* class consists of people who both are "addicted" to nicotine *and* who have suffered some disease claimed to be caused by smoking, which makes it narrower than the *Castano* class.

Last October, the judge certified the class. We have appealed that decision. Arguments on the appeal of the class certification ~~will occur~~ September 27th ~~in the Intermediate Appellate Court in Florida.~~

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The *Engle* plaintiffs seek $100 billion in damages for their physical injuries and for emotional distress, and they ask that the industry be required to establish and finance a medical fund to monitor the health of all class members. They also seek $100 billion in punitive damages.

We believe that both the *Castano* and *Engle* cases are loaded with individual issues -- such as smoking history, attempts to quit, and so on -- that predominate over any common issues.

Exploring these matters would involve individual determinations for each class member, which is exactly what class actions are intended to avoid.

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Even if a class member can prove that he or she was addicted, the class member would also have to prove that the alleged ~~misrepresentations~~ REDACTED of the tobacco industry caused that person to become addicted to cigarettes.

It is not enough for plaintiffs to prove that they are addicted to smoking; they also have to prove that wrongful conduct by the defendants caused them to become addicted.

Proof in this regard raises a host of individual issues, further demonstrating that these cases are not suitable as class actions.

Beyond our arguments against class certification, which we will pursue on appeal, we believe that we have strong defenses on the merits of these cases.

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We have successfully defended addiction claims in prior cases. We believe that potential jurors still believe people can quit smoking if they make the decision to do so.

Furthermore, other defenses, such as assumption of the risk and contributory negligence, are available to us.

And the federal statute that requires the warning labeling on cigarette packs and advertising, provides a strong legal defense, as to "failure to warn" claims.

In summary, then, there is a long way to go on both *Castano* and *Engle*, and for a variety of reasons, we feel confident of our positions and our arguments in both these cases.

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The second type of lawsuit representing a new approach to smoking and health litigation is the Medicaid reimbursement lawsuit.

Since May 1994, four states -- Mississippi, Minnesota, West Virginia, and Florida -- have filed suits seeking to recoup Medicaid and other expenditures for the treatment of diseases allegedly caused by smoking.

It should come as no surprise that these suits rest on theories created by plaintiff attorneys who then sold them to state attorneys general or other relevant state officials and are in fact providing counsel to the state.

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Traditional, individual product liability suits against the tobacco industry have failed largely because juries believe that people freely choose to smoke and knowingly assume any health risks.

The new Medicaid suits, by focusing on the damage to the State and its taxpayers, rather than on the individual smoker, are an effort to avoid this defense.

In May 1994, the Attorney General of Mississippi, filed suit against the leading cigarette manufacturers; The Tobacco Institute; Hill & Knowlton -- a public relations firm that in the past had been hired by The Tobacco Institute; and several cigarette wholesalers, to recoup the costs of health care for persons suffering from alleged tobacco-induced diseases.

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The Governor of Mississippi has filed court papers saying that he was not consulted on and did not approve the filing of the lawsuit by the Attorney General. REDACTED REDACTED REDACTED REDACTED REDACTED REDACTED

The defendants -- including Philip Morris U.S.A. -- filed other motions with the court to dismiss the case or in the alternative to transfer the case to a court in which we would have a jury trial.

The court denied these motions in a one-page memorandum. However, the case is in its ~~the very~~ early stages and we intend to bring these issues before the court again once the record is more fully developed.

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In August the Attorney General of Minnesota -- Hubert H. Humphrey III -- sued the six major U.S. cigarette manufacturers, the Council for Tobacco Research and The Tobacco Institute.

Minnesota's lawsuit includes many unusual claims, and also asks the court to grant unusual forms of relief.

For example, the state is asking the court to make the tobacco industry fund a public education campaign on smoking and health to be administered by an independent third party; to fund "stop smoking" programs in Minnesota; to turn over all profits from cigarettes sales in Minnesota; and to repay the state medical treatment expenses.

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The Minnesota court has denied our motion to dismiss, and the case is now in a very active discovery stage.

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West Virginia's lawsuit is very similar to the one filed by Minnesota. However, West Virginia's Governor, unlike Florida's, has expressed his opposition to the action brought by the Attorney General.

Because we believed the Attorney General did not have authority to bring eight of the ten claims asserted, we moved to dismiss those claims, and the court granted our motion. This has in great part eviscerated the West Virginia lawsuit.

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In sharp contrast to Mississippi and West Virginia, the Governor of Florida Laughton Chiles has warmly embraced the lawsuit against the tobacco industry.

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In fact Governor Chiles was instrumental in arranging for the passage of the Third Party Medicaid Liability Act, which was passed surreptitiously in the closing hours of the 1994 legislative session.

The law is an outrageous, and in our view, unconstitutional attempt to strip the tobacco industry of fundamental due process.

In May, legislation to repeal the law passed the legislature. The house passed the bill 102-13 and the Senate voted 32-7. Governor Chiles then vetoed the bill.

It remains to be seen whether the Governor's veto will be overridden by the legislators during its next session.

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Meanwhile, in June a circuit judge in Tallahassee, Florida declared key provisions of the controversial 1994 amendments to the Florida law unconstitutional.

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The judge also held that the state agency charged with administering the state's Medicaid program is unconstitutionally structured, leading us to believe that the claims based on the Florida Third-Party Medicaid Liability Act should now be dismissed.

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The state is appealing these rulings and the Florida Supreme Court will hear arguments, as well as our appeals on other rulings, on November 6th.

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In summary, then, we believe that we have good defenses to the Medicaid-type lawsuits, even though those suits assert novel theories of recovery.

At bottom, they are attempts to recover payments made for personal injuries, regardless of who made the payments.

Our job is to make the courts see these cases for what they are, and to agree with us that the cases are subject to the same rules of discovery, burdens of proof and defenses available to defendants in all personal injury cases.

Thus far, we've been doing that job pretty well, but a lot remains to be done.

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That concludes my presentation. I thank you for your attention and would be happy to take any questions that you may have.

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